

353 NORTH CLARK STREET, CHICAGO, IL 60654

JENNER & BLOCK LLP

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Dean N. Panos  
Tel +1 312 923 2765  
dpanos@jenner.com

**VIA ECF**

The Honorable Joanna Seybert  
United States District Judge  
U.S.D.C., Eastern District of New York  
100 Federal Plaza, Courtroom 1030  
Central Islip, NY 11722

Re: *In re Hain Celestial Heavy Metals Baby Food Litigation*, Case No. 2:21-cv-678-JS-AYS  
Request for Pre-Motion Conference re: Motion to Stay or Dismiss

Dear Judge Seybert:

I write to request a pre-motion conference in anticipation of The Hain Celestial Group, Inc.'s forthcoming motion to stay and/or dismiss this lawsuit.

Plaintiffs' Consolidated Class Action Complaint ("CCAC") alleges that Hain Celestial's baby food products contain "dangerously high levels" of heavy metals (including lead, arsenic, cadmium, and mercury), as well as perchlorate. CCAC ¶ 13. Plaintiffs allege that these claims render a variety of labeling claims—including indisputably accurate claims like "USDA Organic," "Free of Preservatives or Pesticides," and "Non-GMO," as well as puffery-like claims such as "Made with Superior Ingredients"—false and misleading. *See id.* ¶¶ 4, 103. Plaintiffs also allege that Hain Celestial "omits key information from its product labels regarding contaminants such as Toxic Heavy Metals and/or other toxins to parents' detriment." *Id.* ¶ 102. Based on those allegations, Plaintiffs assert consumer fraud claims under the laws of numerous states, as well as claims for breach of express warranty, breach of the implied warranty of merchantability, negligent misrepresentation, fraudulent concealment, and unjust enrichment. *See id.* ¶¶ 151-468.

Notably, the central premise of Plaintiffs' lawsuit—that Hain Celestial's baby foods contain "dangerously high levels" of heavy metals—directly conflicts with the FDA's finding that "children are not at an immediate health risk from exposure" to the trace amounts of heavy metals in Hain Celestial's baby foods or those of other manufacturers. FDA, *FDA Announces New Actions Aimed at Further Reducing Toxic Elements in Food for Babies, Young Children*, available at <https://bit.ly/3JaQJDC> (last visited Apr. 15, 2022). The FDA has also found, contrary to the allegations of Plaintiffs' CCAC, that "toxic elements are present in the environment, including in our air, water, and soil, and therefore are unavoidable in the general food supply." *Id.*

Given the ubiquity of heavy metals in the food supply, the FDA has emphasized that "[i]t is crucial to ensure that measures taken to limit toxic elements in foods do not have unintended consequences—like eliminating from the marketplace foods that have significant nutritional benefits or reducing the presence of one toxic element while increasing another." FDA, *Closer to*

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*Zero: Action Plan for Baby Foods*, available at <https://bit.ly/3xa0smn> (last visited Apr. 15, 2022). In an effort to address this “complex and multifaceted” issue, the FDA announced its “Closer to Zero” plan in April 2021, which the FDA has described as a “science-based, iterative approach” in which the FDA will set appropriate “action levels” for heavy metals in baby food. *Id.* The FDA held its first public meeting in connection with the “Closer to Zero” plan in November 2021 and is scheduled to hold its second public meeting on April 27, 2022.

Given the FDA’s ongoing efforts to address the presence of heavy metals in baby food, this Court should stay this case pending the FDA’s determination as to appropriate “action levels” for heavy metals in baby food on a going-forward basis. The doctrine of primary jurisdiction authorizes district courts to stay proceedings when resolution of a plaintiff’s claims “requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body.” *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 64 (1956). The Second Circuit has identified four factors courts should consider when deciding whether to stay a case: (1) whether the issue “involves technical or policy considerations within the agency’s particular field of expertise” (2) “whether the question at issue is particularly within the agency’s discretion”; (3) “whether there exists a substantial danger of inconsistent rulings”; and (4) “whether a prior application to the agency has been made.” *Ellis v. Tribune Television Co.*, 443 F.3d 71, 82-83 (2d Cir. 2006) (citation omitted). All four factors favor staying this case:

- Determining appropriate thresholds for heavy metals in food products undoubtedly implicates “technical or policy considerations within the [FDA’s] particular field of expertise” and that are “particularly within the [FDA’s] discretion.” *Id.* The FDA is uniquely well-suited not only to assess the purported risks associated with heavy metals, but also to balance those risks against the benefits of ensuring that babies consume a variety of vegetables, grains, and other nutritious foods. The FDA has made clear that this is a “complex and multifaceted issue,” and it falls squarely within the FDA’s bailiwick.
- Moreover, “the threat of inconsistent rulings may emerge when [an] issue is simultaneously pending before an agency with authority over that same issue.” *Colella v. Atkins Nutritionals, Inc.*, 348 F. Supp. 3d 120, 140–41 (E.D.N.Y. 2018); *see also Ellis*, 443 F.3d at 88 (“Courts should be especially solicitous in deferring to agencies that are simultaneously contemplating the same issues.”). Here, the FDA is actively considering the appropriate “action levels” for heavy metals and baby foods, and it is entirely possible it will determine that the amount of heavy metals in Hain Celestial’s baby foods pose no material risk of harm to consumers and are below the “action levels” it will set. Given the FDA’s ongoing consideration of this issue, it would be imprudent to allow Plaintiffs to press forward with a lawsuit that would potentially require a jury to reach findings that are inconsistent with those of the FDA.
- The “prior applications” factor focuses not on whether the “parties have formally made applications” to the FDA, but instead on whether “the agency’s work is underway.” *In re KIND LLC “Healthy & All Natural” Litig.*, 287 F. Supp. 3d 457, 465 (S.D.N.Y. 2018). There is no dispute that the FDA’s work is underway, as evidenced by its announcement of its “Closer to Zero” plan and its detailed timetable to establish action levels for lead, arsenic, cadmium, and mercury. This factor clearly militates in favor of staying this case.

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Even if the Court were not inclined to stay this case in deference to the FDA’s primary jurisdiction, Plaintiffs’ claims are meritless and implausible. Although Plaintiffs claim that Hain Celestial misled consumers by failing to disclose that its baby foods (like virtually all foods) contain trace amounts of heavy metals, they have not plausibly alleged that this fact is material to consumers—as is required to establish that this alleged omission is deceptive. *See Bildstein v. MasterCard Int’l, Inc.*, 329 F. Supp. 3d 410, 414 (S.D.N.Y. 2004). Given the ubiquity of heavy metals in the food supply and the FDA’s determination that they pose no immediate health risks to consumers, it is implausible that the presence of trace amounts of heavy metals would have any effect on a consumer’s purchasing decision. Under similar circumstances, many courts in New York have dismissed claims premised on the presence of trace amounts of unwelcome substances in food products, holding that the “presence of negligible amounts” of such substances “is not likely to affect consumers’ decisions in purchasing the product[s] and is thus not material.” *Parks v. Ainsworth Pet Nutrition, LLC*, 377 F. Supp. 3d 241, 247–48 (S.D.N.Y. 2019) (dismissing lawsuit premised on alleged presence of supposedly “toxic” pesticide residue in the defendant’s products).

To the extent Plaintiffs allege that the presence of heavy metals renders Hain Celestial’s labeling claims—such as “USDA Organic,” “Free of Preservatives or Pesticides,” and “Made with Superior Ingredients”—false and misleading, those claims fare no better. Courts around the country have made clear that a plaintiff cannot state a consumer fraud claim by alleging that “a consumer will read a true statement on a package and will then . . . assume things about the product *other than* what the statement actually says.” *Red v. Kraft Foods, Inc.*, No. 10-1028, 2012 WL 5504011, at \*3 (C.D. Cal. Oct. 25, 2012). Here, even if Plaintiffs were correct that Hain Celestial’s baby foods contain heavy metals, that does not mean that they are not “organic,” that they contain pesticides or preservatives, or that they do not contain “superior ingredients.”

Indeed, courts have repeatedly rejected similar lawsuits premised on the theory that the presence of allegedly harmful substances prohibits a manufacturer from highlighting its products’ positive attributes. *See, e.g., Parks*, 377 F. Supp. 3d at 247–48 (dismissing consumer fraud claim and holding that the presence of trace amounts of glyphosate did not render the statement “natural” false or misleading); *Song v. Champion Petfoods USA, Inc.*, 27 F.4th 1339, 1343–44 (8th Cir. 2022) (affirming dismissal of consumer fraud claim and holding that the presence of heavy metals did not render the statement “biologically appropriate” false or misleading). And insofar as Plaintiffs challenge the representation that Hain Celestial’s baby foods are “organic,” that theory is preempted because it conflicts with the USDA’s certification of Hain Celestial’s products as “organic.” *See, e.g., Marentette v. Abbott Labs., Inc.*, 201 F. Supp. 3d 374, 385 (E.D.N.Y. 2016).

Finally, leaving aside the merits of their claims, Plaintiffs lack standing to seek injunctive relief, as they cannot “demonstrate that [they are] likely to be harmed again in the future in a similar way.” *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 239 (2d Cir. 2016). Given Plaintiffs’ knowledge that Hain Celestial’s products (and those of its competitors) contain trace amounts of heavy metals, they are now “aware of the truth and will not be harmed again in the same way.” *Davis v. Hain Celestial Grp., Inc.*, 297 F. Supp. 3d 327, 339 (E.D.N.Y. 2018). Thus, at a very minimum, this Court should dismiss Plaintiffs’ claims for injunctive relief.

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Respectfully submitted,

/s/ Dean N. Panos  
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